UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

STANLEY MCFADDEN,)	
Plaintiff,)	
V.)	No. 4:14-CV-803 (CEJ)
3M COMPANY and MINE SAFETY APPLIANCES,)	
Defendants.)	

MEMORANDUM AND ORDER

This matter is before the Court on the motion of defendant Mine Safety Appliances to dismiss for failure to state a claim, pursuant to Fed.R.Civ.P. 12(b)(6). Plaintiff has filed a response in opposition and the issues are fully briefed.

I. <u>Background</u>

Between August 29, 1973 and June 7, 1985, plaintiff Stanley McFadden was continuously exposed to silica dust in the course of his employment. In order to protect him from inhaling silica dust, his employer provided him with respirators designed and manufactured by defendants 3M Company (3M) and Mine Safety Appliances (MSA). He alleges that the respirators failed to work properly and, as a result, he developed pneumoconiosis and/or silicosis. Plaintiff asserts claims against MSA for product liability (Count II), breach of warranty (Count IV), negligence (Count VIII) and negligence *per se* (Count VIII).

Defendant MSA moves to dismiss, arguing that plaintiff's tort claims are completely preempted by the Occupational Safety and Health Act of 1970 (OSH Act), 29 U.S.C. §§ 651 *et al.*, and regulations implemented by the Bureau of Mines

and the National Institute for Occupational Safety (NIOSH). Alternatively, defendant argues that the complaint fails to state a claim for relief under Missouri law.

II. <u>Preemption</u>

A. <u>Legal Standards</u>

The doctrine of preemption, which is derived from the Supremacy Clause, provides that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law must yield." <u>Gade v. National Solid Wastes Mgmt. Ass'n</u>, 505 U.S. 88, 108 (1992) (internal quotations and citations omitted). Consideration of issues arising under the Supremacy Clause "start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." <u>Cipollone v. Liggett Grp., Inc.</u>, 505 U.S. 504, 516 (1992) (citation omitted; alterations in original).

"Preemption may arise in one of three ways." <u>Lindsey v. Caterpillar, Inc.</u>, 480 F.3d 202, 205 (3rd Cir. 2007).

First, courts will find express preemption if Congress has defined explicitly the extent to which a statute preempts state law. Second, in the absence of explicit statutory language, state law is subject to field preemption if it regulates conduct in a field that Congress intended the federal government to occupy exclusively. Finally, state law is preempted to the extent it actually conflicts with federal law. Elec. Co., 496 U.S. 72, 78-79 (1990). Actual conflict arises when it is impossible to comply with both the federal and state laws or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Id. at 79.

<u>Id.</u> at 205-06. A federal agency may preempt state law through its regulations so long as the agency acts within its congressionally-delegated authority. <u>Id.</u> (<u>citing</u> <u>Fid. Fed. Sav. & Loan Ass'n v. De la Cuesta</u>, 458 U.S. 141, 153-54 (1982)).

Defendant relies on the third type of preemption, arguing that plaintiff's tort claims "actually conflict" with federal law.

B. <u>Discussion</u>

The "touchstone" of preemption is congressional purpose. Lindsey, 480 F.3d at 206 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 485-86 (1996)). Congress enacted the OSH Act in 1970, with the purpose "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. § 651(b). Congress also authorized the Secretary of Labor "to set mandatory occupational safety and health standards applicable to business affecting interstate commerce." § 651(b)(3). In doing so, Congress "thereby brought the Federal Government into a field that traditionally has been occupied by the States." *In re* Welding Fume Products Liability Litigation, 364 F. Supp. 2d 669, 674 (N.D. Ohio 2005) (quoting Gade v. National Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 96 (1992)).

The federal entry was not uniform or comprehensive, however. <u>Lindsey</u>, 480 F.3d at 206. First, Congress permitted states to assume responsibility for occupational safety and health by obtaining approval from the Secretary of Labor. § 667(b). This provision is not at issue in this case. Second, the Act preserves to the states the power to "assert[] jurisdiction . . . over any occupational safety or health issue with respect to which no standard is in effect under [the Act]." § 667(a). Finally, the Act includes a "clearly articulated savings clause." <u>Lindsey</u>, 480 F.3d at 206.

¹Although this section does not use the term "preemption," it is considered to have

preemptive effect. See Welding Fume Products, 364 F. Supp. 2d at 674 (referring to § 667(a) as OSH Act's "preemption provision"); see also Nat'l Solid Wastes Mgmt.

Nothing in this chapter shall be construed to supersede or in any manner affect any workmen's compensation law or to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment.

§ 653(b)(4).

"[N]o other enactment contains a saving clause more broad." Welding Fume Products, 364 F. Supp. 2d at 687. Despite its breadth, "[t]he savings clause does not save tort claims that actually conflict with federal regulations." Santos v. Crown Equipment Corp., No. 08-80161-CIV, 2009 WL 1066946, at * 4 (S.D. Fla. Apr. 21, 2009). In assessing whether tort claims "actually conflict" with federal regulations, courts have held that no such conflict is created when the federal regulations "neither require nor forbid particular safety features." Id.

"There is a solid consensus that section [653] (b)(4) operates to save state tort rules from preemption." Pedraza v. Shell Oil Co., 942 F.2d 48, 53 (1st Cir. 1991) (listing cases and finding that OSH Act did not preempt claims brought by worker exposed to chemical); Lindsey, 480 F.3d at 209 (OSHA's rollover-protection regulation did not preempt tort claims brought by estate of worker killed when tractor flipped over); Welding Fume Products, 364 F. Supp. 2d at 690 (OSH Act and Hazard Communication Standard did not preempt claims brought by workers injured by inhaling manganese given off during welding); Santos, 2009 WL 1066946, at *4 (regulation regarding operator enclosures for industrial trucks did not preempt claims brought by worker injured while operating a forklift); Fullen v.

<u>Ass'n v. Killian</u>, 918 F.2d 671, 675 (7th Cir. 1990) <u>aff'd sub nom.</u> <u>Gade v. Nat'l Solid Wastes Mgmt. Ass'n</u>, 505 U.S. 88 (1992) (quoting § 667(a) and (b) as general

preemptive provisions).

Philips Electronics N. Am. Corp., 266 F. Supp. 2d 471, 478-79 (N.D.W. Va. 2002) (OSH Act did not preempt claims brought by workers exposed to multiple hazards); Sakellaridis v. Polar Air Cargo, Inc., 104 F. Supp. 2d 160, 164 (E.D.N.Y. 2000) ("The savings clause plainly states that workers' statutory remedies for personal injuries are preserved. It is not consequential that the standard of care is prescribed by the common law, a separate statutory scheme, or an administrative scheme."); cf. Solis v. Summit Contractors, Inc., 558 F.3d 815, 829 (8th Cir. 2009) ("The federal courts have held that [OSH Act's savings] provision does not create a private cause of action and prevents federal preemption of state tort law and worker's compensation schemes.").

Defendant cites a case in which a court held that a state tort claim actually conflicted with the OSH Act and regulations. In Gonzalez v. Ideal Tile Importing Co., 877 A.2d 1247, 1252 (2005), the New Jersey Supreme Court considered whether the Act preempted tort claims against a forklift manufacturer whose product was in compliance with federal agency standards for warning devices. The plaintiff, who was injured when he was struck by a forklift operated by a coworker, argued that the manufacturer was negligent in failing to include an additional warning device. In determining that the plaintiff's claims were preempted by federal law, the court relied on an agency determination that additional devices should not be used if they would create more dangers than they prevented. Id. at 1252-53. Based on this interpretation, the court found that the federal standards regulated the universe of warning devices. Id.

Defendant argues that plaintiff's state law claims actually conflict with federal regulations governing respirators. In 1971, the Secretary of Labor published

regulations concerning respiratory protection. 29 U.S.C. § 1910.134. The regulation specifies that where atmospheric contamination cannot be prevented through engineering controls, "appropriate respirators" will be used. § 1910.134(a). Employers are required to provide respirators to employees "when such equipment is necessary to protect the health of such employee[s]". § 1910.134(b).² During the course of plaintiff's employment, the Bureau of Mines and NIOSH promulgated regulations governing the design, manufacture, testing, and certification of respirators. See 30 C.F.R. Parts 11 and 14. In relevant part, manufacturers were required to submit an application for certification, accompanied by engineering drawings, testing results, and details regarding quality control and manufacturing processes. See Def. Memo at 7. Once a respirator was approved, it could not be modified without agency approval.³

Defendant asserts that, in order to undertake a proper conflict-preemption analysis, the court must examine the specific standards governing respirators. Despite this assertion, defendant has not undertaken that analysis itself. Rather, defendant draws an analogy between the regulatory scheme here and the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act. Under the MDA, manufacturers of medical devices are required to submit their products to the U.S.

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²Until 1972, the Bureau of Mines was solely responsible for testing and approving respirators. In 1972, the Bureau of Mines and NIOSH jointly published regulations, 30 C.F.R. Part 11 pursuant to which the Bureau of Mines evaluated respirator performance, and NIOSH administered the quality control provisions. In 1972, NIOSH undertook primary responsibility for performance testing of respirators. Respiratory Protective Devices, 59 Fed. Reg. 26892, 26892 (May 24, 1994).

³ The Dustfoe 66 received regulatory approvals effective through June 30, 1975. Def. Memo. at 8-9. It was not approved for use in hazardous atmospheres after that date. <u>Id.</u>

Food and Drug Administration (FDA) for pre-market approval. Riegel v. Medtronic, Inc., 552 U.S. 312, 317-18 (2008). Once approval is given, the medical device may not be altered in any fashion without FDA approval. Id. at 319 (citing § 360e(d)(6)(A)(i)). Under the Supreme Court's interpretation of the MDA, state law claims escape preemption only if the state requirements are equivalent to the federal requirements. McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005). A state law claim that depends upon a finding that the manufacturer should have varied from those "requirements" is preempted. See, e.g., Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206, 1219 (W.D. Okla. 2013) (plaintiff's fraudulent misrepresentation claims preempted by § 360k(a) because they required a finding that the manufacturer should have provided additional warnings above and beyond those on the FDA-approved label).

Defendant argues that, like an approved medical device, its respirator was subjected to regulatory approval and that it could not make alterations without further regulatory approval. Thus, it argues, plaintiff's claims are actually in conflict with the federal standards to the extent that they depend upon a finding that its design was defective. Defendant cites no authority for the proposition that the agency process in and of itself preempts tort claims under the OSH Act. Indeed, work-place safety regulations are so pervasive that, under defendant's argument, the Act would preempt nearly every state law claim.

A regulatory process in and of itself does not create a preemptive effect; rather, preemption arises from the statutory language. The MDA's preemption and savings provisions are much more restrictive than those in the OSH Act. The MDA expressly preempts state law claims that impose a "requirement" that is different

from or in addition to a federal "requirement." ⁴ 21 U.S.C. § 360k(a). The savings provision, found at § 360h(d), ⁵ does not apply to devices subject to the premarket approval process. <u>Goodlin v. Medtronic, Inc.</u>, 167 F.3d 1367, 1378-79 (11th Cir. 1999) (reading 21 U.S.C. 360h(d) to refer "only to compliance with FDA orders regarding notification, repair, replacement, refund, or reimbursement—and not to include compliance with the PMA process, which arises under a different section of the MDA."); <u>see also Talbott v. C.R. Bard, Inc.</u>, 865 F. Supp. 37, 48 (D. Mass. 1994) (§360h(d)applies only to those Class III devices for which a state exemption was obtained). By contrast, here, the pertinent language directs that the Act cannot diminish the common law or statutory rights of employees under any law with respect to employment-related injuries or death. <u>Lindsey</u>, 480 F.3d at 210 (contrasting preemption provision and savings clause in the National Traffic and Motor Vehicle Safety Act of 1964).

The court finds that plaintiff's claims fall within the scope of the OSH Act savings clause and are not preempted.

III. Failure to State a Claim for Relief

Defendant also seeks dismissal pursuant to Fed.R.Civ.P. 12(b)(6). In support of its motion, defendant asserts that its respirator was not unreasonably dangerous as a matter of law, that the plaintiff's breach of warranty claim is barred by the statute of limitations, and that plaintiff cannot establish a claim of negligence

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⁴The Supreme Court has held that the FDA pre-market approval process imposes device-specific "requirements" under the MDA. <u>Riegel v. Medtronic, Inc.</u>, 552 U.S. 312, 322 (2008).

⁵The MDA's savings provision provides: "Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law." 21 U.S.C. § 360h(d). This provision does not apply to devices subject to the premarket approval process.

per se. Whether or not the defendant's product was unreasonably dangerous cannot be determined by the court on the basis of the present record. Likewise, resolution of issues regarding the timeliness of plaintiff's warranty claim and plaintiff's ability to prove negligence per se depends on evidence that has not been presented to the court. A motion to dismiss under Rule 12(b)(6) is not the proper vehicle for evaluating the merits of the plaintiff's claims. Having reviewed the complaint, the court finds that it includes "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007).

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For the reasons discussed above,

IT IS HEREBY ORDERED that defendant's motion to dismiss [Doc. #11] is denied.

CAROL E. JACKSON

UNITED STATES DISTRICT JUDGE

Dated this 3rd day of March, 2015.